THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

Paper No. 21

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

_____

Ex parte GUY T. CARTER,
DAVID R. WILLIAMS
and JOSEPH D. KORSHALLA

_____

Appeal No. 95-4493
Application 07/756,646[1]

_____

ON BRIEF

_____

Before WINTERS, METZ and WALTZ, *Administrative Patent Judges*.

WALTZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 4 and 5, which are the only claims remaining in this application.

[1] Application for patent filed September 9, 1991.

The subject matter on appeal is directed to the antibiotic LL-E19020 $Alpha_1$, its composition and method of use in treating infections. The antibiotic LL-E19020 $Alpha_1$ is the C-21 epimer[2] of known antibiotic LL-E19020 Alpha (specification, page 3). The subject matter on appeal is adequately illustrated by appealed claim 1, which is reproduced and attached to this decision as an Appendix.

The references relied upon by the examiner are:

Carter et al. (Carter) 4,705,688 Nov. 10, 1987

Carter et al. (Carter II), "LL-E19020" and $, Novel Growth Promoting Agents: Isolation, Characterization and Structures", 41 *The Journal of Antibiotics*, no. 10, 1511-1514 (October 1988).

Claims 1, 4 and 5 stand rejected under 35 U.S.C. § 103 as unpatentable over Carter II. Claim 1 stands rejected under 35 U.S.C. § 102(b) as anticipated by Carter[3]. We *reverse* both stated rejections.

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[2] An epimer is an isomer which differs from the compound with which it is being compared only in the relative positions of an attached hydrogen and hydroxyl. The isomerism may be represented as -HCOH- and -HOCH-. *See The Condensed Chemical Dictionary*, page 343 (Ninth Ed., Van Nostrand Reinhold Company, 1977).

[3] This rejection was a new ground of rejection made for the first time on page 5 of the examiner's answer.

OPINION

A. The Rejection under 35 U.S.C. § 103

The claimed antibiotic compound LL-E19020 alpha$_1$ (hereafter "alpha-1") is the C-21 epimer of the known antibiotic LL-E19020 alpha (hereafter "alpha"). Alpha-1 is prepared by the process set forth on pages 10-13 of the specification.

Carter II describes the discovery of antibiotic alpha and its preparation on page 1511.

From the properties recited for alpha in the Carter II article and those properties of alpha-1 recited in appealed claim 1, it is apparent that the examiner and appellants agree that alpha and alpha-1 are different compounds but have the same structural formula. As stated by the examiner, the "sole difference" between the prior art and the claimed compound "lies in the configuration of the trisaccharide moiety at the C-21 position" (answer, page 4).

The examiner concludes that the claimed compound "is rendered obvious" because the prior art compound is "structurally similar" and both "possess similar antibacterial properties" (answer, page 4). The examiner states that "the courts have consistently held that if the claimed invention is structurally

similar to the prior art compound, non-obviousness can exist only if this novel structure produces results unexpectedly different from those of the prior art" (answer, page 7).

Contrary to this assertion by the examiner, the court has held that, irrespective of any close structural similarity, it is essential that the prior art applied by the examiner disclose or render obvious a method for making the claimed compounds. As stated by the court in *In re Hoeksema*[4]:

> Thus, upon careful reconsideration it is our view that if the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public [footnote omitted]. In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on close relationships between their structures and those of prior art compounds.

See also In re Payne, 606 F.2d 303, 314-15, 203 USPQ 245, 255 (CCPA 1979), and *In re Brown*, 329 F.2d 1006, 1011, 141 USPQ 245, 249 (CCPA 1964). References relied upon to support a rejection under 35 U.S.C. § 103 must provide an enabling disclosure, i.e., they must place the claimed invention in the possession of the public. *In re Payne*, 606 F.2d at 314, 203 USPQ at 255.

[4] 399 F.2d 269, 274, 158 USPQ 596, 601 (CCPA 1968).

Appellants argue that there is a lack of enabling disclosure in the applied prior art (brief, page 4). The compound alpha-1 is a natural product made by fermentation of *streptomyces lidicus* ssp. *tanzanius*. As noted by the examiner (answer, page 10), appellants and Carter II ferment the same microorganism. However, without the use of hindsight from appellants' specification, there is nothing in the Carter II reference that discloses or suggests that an epimer of alpha can be obtained from the method disclosed by the Carter II reference. It is improper for the examiner to use hindsight based on information gleaned only from appellants' disclosure. *See In re McLaughlin*, 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971).

The examiner alleges that preparing the claimed invention is considered within the "purview of the skilled artisan because both the claimed and the prior art compounds are obtained by the fermentation of the same *Streptomyces lydicus* sp." and "resolution of various epimers is also considered to be within the purview of the skilled artisan" (answer, page 10).

Even though the claimed and prior art compounds are concededly obtained from fermentation of the same microorganism, the process of preparation disclosed by appellants is markedly different from that disclosed by Carter II. For example, the

nutrient mediums employed are different, appellants combine two fermentations while Carter II apparently only uses one fermentation, and appellants recognize that fraction 7 contains impure alpha-1 and purify it using a particular process to isolate certain fractions (see the specification, page 12) while Carter II does not isolate any fraction or use any further purification procedures.

Furthermore, the examiner has not cited any evidence to support the allegation that resolution of epimers is within the ordinary skill of the art.

For the foregoing reasons, we hold that the disclosure of Carter II does not place alpha-1 in the possession of the public at the time appellants' invention was made. Accordingly, the rejection of claims 1, 4 and 5 under 35 U.S.C. § 103 as unpatentable over Carter II is reversed.

B. The Rejection under 35 U.S.C. § 102(b)

The examiner has rejected appealed claim 1, directed to the alpha-1 compound, as being anticipated by Carter since "the instant compound is obtained from the same strain, by the same process and as such is inherently present in the prior art concentrate" (answer, paragraph bridging pages 5-6).

Appellants' response to this new ground of rejection is that the law is clear that for a rejection based upon inherency to be sustained, the inherency must be an inevitable result and not merely a probability or possibility (reply brief, paragraph bridging pages 2-3). Appellants argue that the presently claimed alpha-1 material was not recognized or identified in Carter. Thus it is not certain or inevitable that alpha-1 was present in the fermentation materials produced in Carter and a rejection based upon inherency is not proper (reply brief, page 3).

For a reference to anticipate a claim, "the disclosure need not be express, but may anticipate by inherency where it would be appreciated by one of ordinary skill in the art." *Glaxo Inc. v. Novopharm Ltd.,* 52 F.3d 1043, 1047, 34 USPQ2d 1565, 1567 (Fed. Cir. 1995), *cert. denied,* 116 S. Ct. 516 (1995). As correctly stated by appellants, the inherency must be an inevitable result and not merely a possibility. *See In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981).

The process of preparing compounds alpha and beta of Carter is markedly different than the process of preparing alpha-1 disclosed by appellants (as specifically set forth on pages 10-13 of the specification). Appellants' process does not use a silica column purification as set forth by Carter at column 8, lines 31-

42. Appellants and Carter do use the same reverse-phase column purification (compare column 8, lines 43-49, with the specification, the paragraph bridging pages 11-12). However, appellants then proceed with further purification using chromatographic techniques (specification, page 12, line 6 to page 13, line 17).

The examiner concludes that "inherency is a certainty" because both the prior art and the instant process use the identical microorganism strain and "subject it [to] substantially identical fermentation procedures" (examiner's response to reply brief, page 3). However, it is clear from the above comparison of the processes of Carter and appellants that the fermentation procedures are not "substantially identical" and it has not been shown by the examiner that it is inevitable that the same products would be produced by each process. Therefore, the examiner has not shown that the compound of appealed claim 1 is inherently produced by the prior art process.

Rejection for anticipation requires, as noted above for section 103 rejections, that a reference must describe the applicants' claimed invention sufficiently to have placed a person of ordinary skill in the art in possession of it, i.e.,

the reference must contain an enabling disclosure. *See In re Spada*, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990). Appellants argue that the teaching of Carter is not enabling for the separation of alpha-1 compound from the alpha and beta components (reply brief, page 2). The reply to this argument by the examiner is that "it is a matter of routine separation to isolate the various components so formed" (examiner's response to reply brief, page 2). However, the examiner has presented no evidence that a skilled artisan would expect epimers to be produced and would know how to isolate and purify them from such a fermentation mash process. *See In re LeGrice*, 301 F.2d 929, 936, 133 USPQ 365, 372 (CCPA 1962)(A reference anticipates a claim if it discloses the claimed invention "such that a skilled artisan could take its teachings in *combination with his own knowledge of the particular art and be in possession of the invention."*, emphasis in original).

Even assuming *arguendo* that the alpha-1 product was produced by Carter, there was no recognition by Carter that any fraction contained a useful product other than the alpha and beta compounds in fractions 7 and 11-13, respectively (see column 8, lines 47-49). Carter does not recognize or appreciate that alpha

has an epimer, that the epimer was produced by the process of Carter, or how to isolate and purify any such epimer if present.

The examiner states that "unrecognized and unappreciated co-production of a chemical by a process does not bar a patent on the later invention of the same product", citing *Silvestri v. Grant*[5], but limits this principle of law to duplications of an invention that are "both accidental and unappreciated" (emphasis examiner's, answer, page 6). The examiner concludes that the production of the claimed compound, though unappreciated, is "by no means accidental" (answer, page 6).

Contrary to the examiner's interpretation, any production of alpha-1 by Carter would be considered accidental and unappreciated. Carter never recognized that epimers of alpha exist or how to isolate and purify them. As conceded by the examiner, any production of alpha-1 by Carter was unappreciated (examiner's response to reply brief, page 1). This result may also be considered "accidental", i.e., not intended and not appreciated. *See Eibel Process Co. v. Minnesota & Ontario Paper Co.,* 261 U.S. 45, 43 S. Ct. 322 (1923). A prior achievement of a product may be considered accidental if it was a consistent

[5] 496 F.2d 593, 596, 181 USPQ 706, 708 (CCPA 1974).

though unintended or incidental consequence of what was deliberately intended[6]. It is clear that any production of alpha-1 by Carter was unintended or incidental to the deliberate production of alpha and beta.

For the foregoing reasons, the rejection of claim 1 under 35 U.S.C. § 102(b) as anticipated by Carter is reversed.

REVERSED

SHERMAN D. WINTERS Administrative Patent Judge	)	
ANDREW H. METZ Administrative Patent Judge	)	BOARD OF PATENT APPEALS AND INTERFERENCES
THOMAS WALTZ Administrative Patent Judge	)	

[6] *Chisum on Patents*, Vol. 1, § 3.03[2], p. 3-37 (Matthew Bender, 1997).

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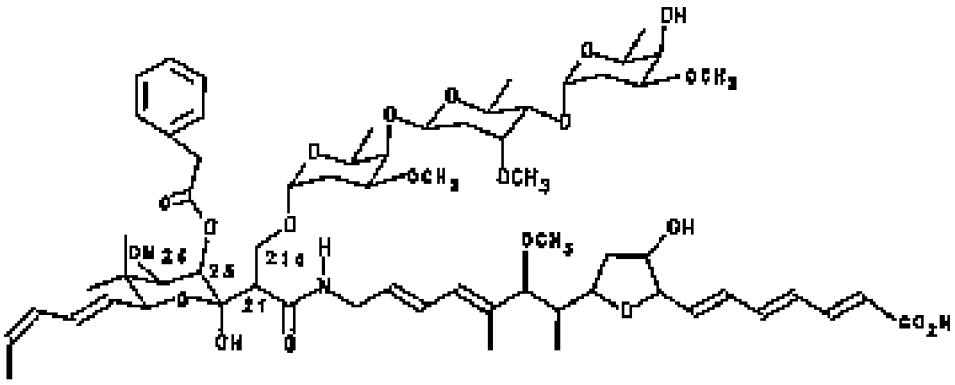
APPENDIX

1. A compound LL-El9020 Alpha$_1$ comprising

(a) the structure



(b) a molecular weight of 1225 (FABMS = M/Z 1248 corresponding to [M+Na]+);

(c) a molecular formula: $C_{65}H_{95}NO_{21}$

(d) a characteristic ultraviolet absorption spectra as shown in Figure I of the attached drawings;

(e) a charateristic infrared absorption spectrum as shown in Figure II of the attached drawings;

(f) a characteristic proton nuclear magnetic resonance spectrum as shown in Figure III of the attached drawings; and

(g) a characteristic carbon-13 nuclear magnetic resonance spectrum as shown in Figure IV of the attached drawings;

(h) a characteristic HPLC retention time of 23.1 minutes using a gradient of dioxane in aqueous acetic acid.